CHRIS MIKSON

PRACTICING AT THE INTERSECTION OF LAW AND MEDICINE

Perspectives spoke with Litigation & Dispute Resolution partner Chris Mikson (DC), whose training as a physician, registered patent attorney and trial lawyer has opened doors to a colorful and fulfilling career.

INTERVIEW BY GEOFF BASZCZUK, ASSISTANT DIRECTOR OF BUSINESS DEVELOPMENT & MARKETING IN OUR NEW YORK OFFICE

WHAT CAME FIRST—YOUR INTEREST IN MEDICINE OR LAW?

I was always interested in both. I had been trained in first aid and CPR in my teens, and as an ocean lifeguard I made rescues where I had to administer first aid for some pretty severe injuries, including a victim with a broken neck, which piqued my interest in medicine. By the same token, in my junior year of high school I received a traffic citation for a collision that was not my fault. I took the matter to court myself on my 18th birthday and won my case. The fact that I had the ability to change a legal outcome to the correct one fascinated me and made me interested in becoming a trial lawyer.

BEFORE MEDICAL SCHOOL, WAS YOUR LEGAL PRACTICE FOCUSED ON PHARMACEUTICALS, BIOLOGICS AND MEDICAL DEVICES OR WERE YOU A GENERAL PRACTITIONER?

I joined a large Philadelphia law firm and practiced general commercial litigation. Most of my cases involved business disputes, personal injury cases or insurance coverage litigation. One of my cases involved a complicated insurance claim for medical malpractice. I needed to learn the basic science of the drug's effect on the body, the clinical basis for its administration (and thus the medical error) as well as the governing legal and regulatory standards, which was when I began thinking that law and medicine could be a fascinating combination.

WHAT MADE YOU FINALLY GO FOR YOUR MEDICAL DEGREE?

When I was a third-year associate, my roommate was riding his bicycle and was run off the road by a delivery truck and hit his head. When I went to the emergency department to see him, there was only a single resident on duty. We had mutual friends, and when I told him I had always been interested in medicine, he asked me to "assist" him by holding a set of forceps in position while he located and sutured a ruptured artery beneath the skin in the patient's forehead. That was it for me. My earlier interest in medicine came rushing back to me, and I decided right there I was going back to school.

HOW DID YOUR PRACTICE CHANGE ONCE YOU RECEIVED YOUR M.D.?

Holding the medical degree opened up a whole new world of legal practice for me. The summer before I started medical school, I took and passed the patent bar. Then, in my first month of medical school, I was hired by a global firm to work part-time handling patent prosecution and litigation. They set me up in an office and paid me $100 for every hour I billed. Besides making me the highest-paid student in my medical school class (for which my friends in medical school constantly harassed me), that made me realize that combining medicine and law was a realistic pathway and offered a fascinating practice opportunity. I joined that firm full-time when I received my M.D. When working on a medical device patent case several years later, I decided to research the US Food and Drug Administration (FDA) regulatory history of the device to see what the patentee had submitted to the agency, and I discovered some evidence in the regulatory filings that was helpful to our client on the patent issues. That is when the idea of practicing at the intersection of patent law and FDA law came into clarity for me.

DESCRIBE THE MOST INTERESTING MATTER YOU'VE WORKED ON SINCE JOINING THE FIRM IN 2015?

Earlier this year, I worked on a case for a global company that sells food, dietary supplements and some drugs. They had come up with a new product that was a dietary supplement for regulatory purposes, but they had undertaken clinical studies to support certain health claims the company wanted to make. As they were getting close to product launch, a major study came down in a scientific journal that found that one of the ingredients in the product caused serious health problems in a specific, well-defined subset of the population. I had to advise the client on the best short-term and long-term strategies to maximize the possibility of success with the product while minimizing the risk of regulatory enforcement, product liability and patent infringement. The work required assessing a variety of clinical trials that had been performed; considering additional clinical trials that might be helpful; as well as coordinating the regulatory, product liability and intellectual property strategies. It was a great example of how these seemingly discrete areas are actually closely interrelated and must be carefully assessed and planned together.

WE UNDERSTAND THAT YOU SEE MAJOR TRENDS IN THE BIOLOGICS/BIOSIMILARS SPHERE. HOW WILL THOSE DEVELOPMENTS IMPACT THE FIRM'S LIFE SCIENCES CLIENTS?

I was fortunate to become involved with biosimilars (a biosimilar is a close but not identical copy of an original biologic drug that is manufactured by a different company) at a very early stage, when the proposals for biosimilars legislation were first being made, several years before the US Biosimilars Price Competition and Innovation Act was passed in 2010 as part of the Affordable Care Act. It was immediately clear to me that this legislation, when passed, would be a watershed event for the drug and biologics industries, as well as for patient care, much as Hatch-Waxman had been after it was passed in 1984. I have worked on a variety of regulatory and patent matters involving biosimilars since the law was passed, and this area of the law has become more and more active, particularly in the past year since a pivotal decision by the US Supreme Court. Since biologics are becoming a more significant focus of the drug industry than small molecules, I believe many of our life sciences clients are going to need to consider the potential for, and impact of, biosimilars in their product spaces. Interestingly, the traditional bright line between the brand and generic sides seems to be blurred somewhat in the biologics/biosimilars space, as companies that are traditionally considered brand companies are coming up with biosimilars, and vice versa. This blending of the two sides will certainly have an impact on how our clients make their strategic plans and their relationships with the law firms they work with in this area.

WHAT CHANGES HAVE YOU SEEN SINCE SCOTT GOTTLIEB'S APPOINTMENT AS FDA COMMISSIONER? WHAT DO YOU THINK HIS BIGGEST IMPACT WILL BE?

Dr. Gottlieb has a unique combination of education and experience that make him particularly well suited to lead the agency as the industries it regulates become more and more diverse and complicated. He is known for a number of plainspoken statements on the need for change in the regulation and approval of therapeutics in this country and is leading changes in a variety of areas that are of great importance to our clients. It is well known that he is spearheading a variety of efforts to decrease drug costs, in part by increasing the availability of generic drugs and biosimilars. One area where the agency is being particularly flexible and transparent is in the field of regenerative medicine. I was recently on a panel with Dr. Peter Marks, the director of FDA's Center for Biologics Evaluation and Research (CBER), and he was describing in detail how the agency was working to partner more directly with innovators in this area and to help with the development of new technologies and research approaches that would allow more certainty and predictability in the approval process. I think the most significant impact of Dr. Gottlieb's tenure will be that therapeutics will be brought to market more quickly and efficiently with minimal impact on safety, thus maintaining and enhancing our position in the world as a center of medical innovation and ever-improving patient care and outcomes.

HOW HAS YOUR UNIQUE BACKGROUND SHAPED YOUR TIME AT MAYER BROWN? ARE YOU PULLED IN MULTIPLE DIRECTIONS BY YOUR TRANSACTIONAL, ADVERSARIAL AND IP PEERS?

Because of my background, I am fortunate to be included in a stunningly diverse collection of matters with practitioners from all over the Firm, both geographically and by practice specialties. I am involved in a large number of transactional matters, from supply and service agreements, to clinical trial protocols, to diligence of major transactions in the life science and medical device industries. I am also involved as a litigator in a number of cases in federal court involving claims involving drugs and devices, for example, product liability cases as well as business and consumer actions seeking damages based on alleged regulatory infractions. I also work very closely with our intellectual property practitioners in patent litigation matters as well as a wide variety of counseling and transactional matters where the FDA regulatory and clinical or scientific issues are intertwined with the patent issues.

WHAT MAKES YOU MOST EXCITED ABOUT THE FUTURE OF YOUR PRACTICE?

I never know what is around the next corner. I am frequently awed by the innovations that I encounter with our clients in the basic sciences, technology and engineering, as well as in clinical research and the clinical practice of medicine. It is fascinating, and truly an honor, to be in the position of helping innovators in these fields develop a therapeutics and guide them through all the legal, regulatory and scientific issues they encounter on the path to bringing a new medicine or medical device to market and to the patient population. ◆